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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,679	03/18/2004	Andrew D. Sutton	263742002802	8165
25226 7590 04/16/2007 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/804,679	Applicant(s) SUTTON ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-24 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,22-24 and 26-33 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/1/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 20, 22-24 and 26-34 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on February 1, 2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Request for Continued Examination (RCE)

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 29, 2007 has been entered.

Action Summary

3. The rejection of claims 20, 22-23 and 26-31 under 35 U.S.C. 102(e) as being anticipated by Platz et al. is being maintained for the reasons stated in the office action dated September 27, 2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 20, 22-24 and 26-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Platz et al. (US 6,509,006 B1).

Platz et al. disclose a pharmaceutical-based dry powder composition for pulmonary delivery, wherein the composition comprises a therapeutically effective amount of a pharmaceutical in combination with a pharmaceutically acceptable carrier (col. 5, lines 63-67). Column 8 line 67 through column 9, line 7 teach the preferred particle size as being less than 10 microns. Column 6, lines 1-13 teach the pharmaceutical as a protein, peptide or enzyme. Column 6, lines 27-34 teach the carrier in amounts from 0.05% to 99.5%. Column 6, lines 35-67 through column 7, line 6 teach the carrier as an excipient, such as, bulking agents for example carbohydrates, polysaccharides, mannitol, etc. Column 7, lines 27-56 teach a dry powder inhaler for the composition. Column 7, lines 7-11 teach the addition of additives the can improve dispersibility of the powder.

Response to Arguments

5. Applicant's arguments filed February 1, 2007 have been fully considered but they are not persuasive.

Applicants argue that the prior art reference of Platz et al. does not qualify as prior art under 35 U.S.C. 102(e) using the filing date of July 8, 1992 of UK 9107628.1 (UK '628) because the UK document had a priority date of April 10, 1991. The examiner disagrees. A review of UK 9107628.1 indicates that there is no support a water-soluble microparticle comprising a water-soluble carrier and an therapeutic agent for administration via the pulmonary airways therefore the applicant does not get priority back to April 10, 1991. UK '628 is directed towards the preparation of diagnostic agents used to enhance ultrasound imaging. The microcapsules of UK '628 do not contain a protein, peptide or enzyme as an active agent. UK '628 teaches the use of a protein as a wall forming material, not as a therapeutic agent as claimed in the instant invention. Furthermore, the microparticles of UK '628 delivers the microcapsule via injection whereas the instant invention delivers the microcapsules via the pulmonary airways. A review of priority document US Patent 5,518,709, applicants, are not entitled to a filing date of March 15, 1993 for the same reasons stated for the UK '628 document. The earliest priority date that will be given for this application is June 7, 1995. Platz et al. qualifies as prior art against the instant application because it has a filing date that dates back to July 8, 1992.

Applicants argue that Platz et al's. priority document (07/910,048 now USP 5,458,135) does not teach the composition as claimed. It is also argued that Platz et al.

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can't be used if the priority document does not teach or suggest the invention as claimed. USP '135 teaches in column 5, lines 51-67 that the device is designed to deliver medicaments, drugs bioactive agents (i.e. proteins or polypeptides) to the lungs as an aerosol bolus of either a liquid or powder. Column 12, lines 24-27 teaches spray drying the powder with a solution of a carbohydrate (mannitol) and bovine serum. With this disclosure it is the position of the examiner that the limitations of the claims are met and USP '006 can be used against the instant invention. Applicant argues that the bovine serum is acting as a carrier. It is the position of the examiner that since the particles contain a drug (i.e. protein) and a carbohydrate (i.e. mannitol) it reads on the claimed invention no matter how the carbohydrate is being used.

Thus the instant invention remains anticipated by the prior art and as such claims newly added claims 32 and 33 are also rejected.

Conclusion

6. Claims 20, 22-24 and 26-33 are rejected.

Allowable Subject Matter

7. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a composition for pulmonary delivery of a water-soluble microparticles comprising a water-soluble carrier and a therapeutic agent, wherein the carrier is selected from a simple or complex

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carbohydrate and the agent is a protein, peptide or enzyme and wherein the microparticle further comprises a phospholipid. Platz et al. teaches the use of additives in the formulation, however, Platz et al. does not teach or suggest the use of phospholipids in the formulation.


Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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